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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,593	10/13/2000	Osamu Ietsu	M-9005 US	9434

22798 7590 09/24/2003

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
P O BOX 458  
ALAMEDA, CA 94501

EXAMINER
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KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/687,593

Applicant(s)

TETSU ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1-20 are pending in the present application. Upon reconsideration of the finality of the Office action mailed May 20, 2003 and the arguments presented in the interview on July 8, 2003, the finality of the prior Office action of May 20, 2003 has been withdrawn and an action on the merits is found below.

#### ***Status of the Claims***

The rejection of claims 1-20 under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) over Karin et al (USP 6,242,253) have been withdrawn because Karin et al. fails to disclose a two-hybrid assay system using a mammalian two-hybrid assay system nor does it describe a system which measures the degradation deficiency of the metabolic product.

The rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification have been withdrawn upon further consideration of the specification. Support for the term has been found.

Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572) for reasons of record and as further discussed below.

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***Claim Rejections - 35 USC § 103***

Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572).

Applicant argues in Paper No. 18 that Barker et al. fail to teach the screening method with mammalian cells. Barker does indeed teach a mammalian two-hybrid system using modified cells. Although Barker et al. considers the Tcf reporter expression not necessarily the beta-catenin degradation product, Barker et al. does render obvious the present claims as well. Barker et al. teach that "compounds can be tested for the ability to inhibit the binding of beta-catenin and Tcf-4, thus mimicking the action of APC. Such a test can be conducted *in vitro* or *in vivo* for example using a two hybrid assay." In order to test for compounds which mimic the action of APC, APC<sup>-/-</sup> mutant or modified cells would be required. Thus, it would have been obvious to one of ordinary skill in the art to use APC<sup>-/-</sup> cells, mammalian cells in the present method. Moreover, the only such cells exemplified throughout Barker et al. are carcinoma cell lines including SW480, SW620, DLD-1 and HT29-APC<sup>-/-</sup> were exemplified and taught in Barker et al. See column 8, line 56 and especially column 9, line 12. Yeast or other eukaryotic cells for assaying test compounds are not mentioned anywhere in the discussion of Barker et al. Sadowski et al, Young, Finley et al, Hagahara et al Schwarze et al. are cited for the reasons already of record and outlined again below. As discussed in prior Office actions, these references teach the various components necessary and well-known in two-hybrid screening techniques such as inducible promoters to permit transient expression of toxic proteins, See Finley, page 199, transcriptional repression domains because it relies on a positive signal, See

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Sadowski col.3-col.4, or using an HIV-TAT domain to promote internalization of proteins into virtually any cell type.

Therefore, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
September 22, 2003

JAMES KETTER  
PRIMARY EXAMINER